In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 00-179V April 11, 2007

ORDER TO SHOW CAUSE¹

Petitioner filed a petition on April 3, 2000, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered on April 20, 1998 and May 20, 1998 caused her unspecified injury. She later alleged multiple sclerosis (MS).

FACTS

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioner was born on December 4, 1961. The undersigned has not found proof of vaccination in the records petitioner filed.

On July 26, 1998, two months after her alleged second hepatitis B vaccination, petitioner noted retro-orbital pressure in her left eye followed by decreased visual function. Med. recs. at Ex. 1, p. 51. Initial pressure sensation improved with antihistamines. On July 27, 1998, she noted a curtain over the superior visual field in her left eye which gradually progressed. She saw Dr. Linda Angell on July 30, 1998 on an emergency basis. She told Dr. Angell she had a gray spot field of vision with sudden onset. Med. recs. at Ex. 6, p. 24. She had no history of headache, dizziness, or previous blurred vision, diplopia, numbness or weakness, of even a transient nature. Med. recs. at Ex. 1, p. 51. She saw Dr. Eric R. Eggenberger for a neuro-ophthalmologic evaluation on August 4, 1998 and he diagnosed her left eye with retrobulbar optic neuropathy, most logically optic neuritis. *Id*.

On January 25, 1999, petitioner had an MRI scan of her brain which was negative. Med. recs. at Ex. 1, p. 65. There was an abnormal signal in the upper cervical spinal cord which was improved when compared to a previous MRI of December 31, 1998. *Id.* Dr. David I. Kaufman diagnosed neurologic syndrome involving petitioner's optic nerves and spinal cord. The cause could be Devic's syndrome (neuromyelitis optica) secondary to MS. However, sarcoid or other etiologies could not be eliminated. *Id.* Petitioner also had a right lumbosacral radiculopathy most likely corresponding to a right L5-S1 nerve root abnormality. A mildly axonal primary motor peripheral polyneuropathy might be possible. *Id.*

On June 25, 1999, petitioner saw Dr. Daniel L. Murman, a neurologist. Med. recs. at Ex. 1, p. 69. She had been hospitalized in April for significant worsening of her myelitis resulting in

quadriparesis and sensory loss below the cervical region. On June 15, 1999, petitioner developed blurring of her right eye. *Id*.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In <u>Capizzano v. Secretary of HHS</u>, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." <u>Grant, supra,</u> at 1149. Mere temporal association is not sufficient to prove causation in fact. <u>Hasler v. US</u>, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have MS, but also

that the vaccine was a substantial factor in bringing about her MS. Shyface v. Secretary of HHS,

165 F.3d 1344, 1352 (Fed. Cir. 1999).

Here, assuming petitioner proves she received hepatitis B vaccination, her onset of

Devic's disease (a variant of MS) was two months after her second vaccination. In Werderitsh v.

Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the

undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. However, the

onset interval after vaccination in Werderitsh was one month. Dr. Roland Martin, respondent's

expert, testified in Werderitsh that an appropriate temporal interval for an immune reaction

would be a few days to three to four weeks.

The undersigned doubts that petitioner will find an expert to state that petitioner's

hepatitis B vaccination two months before the onset of her Devic's disease caused it.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by

June 1, 2007.

IT IS SO ORDERED.

<u>April 11, 2007</u>

DATE

s/Laura D. Millman

Laura D. Millman

Special Master

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